| AL |) | |
|----|---|--|
| | | |

Award Number: DAMD17-01-1-0822

TITLE: Analysis of Activity Patterns and Performance in Polio

Survivors

PRINCIPAL INVESTIGATOR: Mary Klein, Ph.D.

Mukul Talaty, Ph.D.

CONTRACTING ORGANIZATION: Albert Einstein Healthcare Network

Philadelphia, Pennsylvania 19141

REPORT DATE: October 2003

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;

Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

| 1. | A | GEN | ICY | US | Ε | ONLY | |
|----|-----|-----|------|-----|---|------|--|
| (| Lea | ave | blai | nk) | | | |

2. REPORT DATE October 2003 3. REPORT TYPE AND DATES COVERED
Annual (15 Sep 02-15 Sep 03)

4. TITLE AND SUBTITLE

Analysis of Activity Patterns and Performance in Polio Survivors

5. FUNDING NUMBERS
DAMD17-01-1-0822

6. AUTHOR(S)

Mary Klein, Ph.D. Mukul Talaty, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Albert Einstein Healthcare Network Philadelphia, Pennsylvania 19141 8. PERFORMING ORGANIZATION REPORT NUMBER

E-Mail: mklein@einstein.edu

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

The goals of this project are: 1) to study the temporal relationship between activity level and health status in polio survivors and to compare the results with those obtained from an age-matched control population and 2) to look at the effect of localized muscle weakness and the associated compensation response on performance of a walking task. Simulation modeling techniques will be used to identify factors critical to task performance, which will provide valuable information for optimizing rehabilitation interventions for polio survivors and other populations with lower extremity muscle weakness. To date, a total of 43 polio survivors and 63 controls have been enrolled and tested for Study #1. Preliminary data analysis has begun. An improved baseline has been developed for the simulation model in Study #2. Sensitivity analysis of the model has been completed. Initial IDA assessment of model performance has been performed, and perturbation analysis and interpretation are underway.

| 14. SUBJECT TERMS Polio survivors; physi | 15. NUMBER OF PAGES 51 | | |
|--|---|--|--------------------------------------|
| | | | 16. PRICE CODE |
| 17. SECURITY CLASSIFICATION OF REPORT Unclassified | 18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified | 19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified | 20. LIMITATION OF ABSTRACT Unlimited |

Table of Contents

| Cover1 |
|--|
| SF 2982 |
| Introduction4 |
| Body4 |
| Key Research Accomplishments9 |
| Reportable Outcomes9 |
| Conclusions10 |
| Appendix I Inclusion/Exclusion Criteria for Study #1 |
| Appendix II Data Collection Forms for Study #1 |
| Appendix III Copy of conference paper for Study #2 |

INTRODUCTION

Controversy exists regarding the relationship between strength, functional performance, and health status in the post-polio population, and the role of activity level in this relationship. Polio survivors tend to have a higher incidence of muscle and joint pain and higher levels of fatigue after normal daily activity compared to the general population. One possible explanation is that, because of their residual muscle weakness, polio survivors perform their activities at a higher activity intensity level than their peers, which may, in turn, make them more susceptible to musculoskeletal problems. However, there have not been any systematic studies performed to confirm this theory. Therefore, one of the goals of this project is to study the temporal relationship between activity level and health status in polio survivors and to compare the results with those obtained from an age-matched control population. A need also exists for improved neuromuscular, musculoskeletal, and link segment dynamic models of common daily activities that can be used to predict the compensatory strategies that will be employed when muscle weakness is present. Therefore, another goal of this research is to look at the effect of localized muscle weakness and the associated compensation response on performance of a walking task. Simulation modeling techniques will be used to identify factors critical to task performance, which will provide valuable information for optimizing rehabilitation interventions for polio survivors and other populations with lower extremity muscle weakness.

BODY

Study #1: An Analysis of Health Status and Activity Level in Polio Survivors Over Time

Although the funding for this study was approved in Sept. 2001, negotiations between the administration for the Albert Einstein Healthcare Network and the contracting office for the Department of the Army regarding language included in the grant agreement resulted in a delay in the signing of the final contract to be held up until mid-Sept. 2002. At that time, the inclusion and exclusion criteria were operationalized (Appendix I) and the data collection forms were developed (see Appendix II). We have now just completed our first year of testing.

As of Sept. 10, 2003, a total of 106 subjects had completed at least one of the four required visits. Visit information is summarized in Table 1 and demographic information is listed in Table 2. Of the 43 polio survivors enrolled in the study so far, all but nine reported symptoms of post-polio syndrome.

Table 1. Number of Subjects Who Completed Each Visit as of 9/10/03

| Group | Visit 1 | Visit 2 | Visit 3 | Visit 4 |
|------------|---------|---------|---------|---------|
| Post-polio | 43 | 39 | 28 | 4 |
| Control | 63 | 26 | 12 | 1 |

Table 2. Descriptive Statistics

| Variable | Post-Polio | Control |
|---|--|--|
| # enrolled Gender Age Range (yr) Age (Mean(SD)) | 43 M-23, F-20 50-81 64.54 (8.1) | 63 M-22, F-41 53-89 72.40 (7.9) |
| PACE score Steps/day | 147.59 (104.1) 3320.63 (1411.3) | 162.11 (80.4) 4793.41 (1667.2) |

Preliminary data analysis has begun. Analysis of the step monitor data revealed that polio survivors were inactive about 80% of the time, compared to 76% for the controls. For the polio survivors, the greatest proportion of active time was spent at the "low" level, which is defined as less than 15 steps per min and is associated with intermittent activity. Controls, on the other hand, spent the greatest amount of time at the "high" level, which is defined as greater than 30 steps per minute. Controls also had a higher activity frequency level, as measured by both the step monitor in terms of average steps per day and the PACE score, than polio survivors. An estimate of activity intensity was calculated by dividing normal walking speed by maximum walking speed. While polio survivors reported higher mean activity intensity levels on average, there was no significant difference in activity intensity between groups (Mann-Whitney U test statistic = 1210.00, p = 0.127).

The preliminary analysis of the fatigue severity data revealed a significant difference in baseline total fatigue between groups (Mann-Whitney U test statistic = 1007, p = 0.008). The mean fatigue score for polio survivors was significantly higher than that for the controls (34.95 vs. 27.52). One of our a priori hypotheses was that subjects with high activity frequency levels and high activity intensity levels would report greater fatigue than subjects with high activity frequency levels and low activity intensity levels. The reasoning was that subjects who are very active and also work at a level closer to their maximum capacity will be more likely to experience problems related to overuse and report higher levels of fatigue. A preliminary analysis was performed to test this hypothesis, where subjects were ranked with regard to activity intensity and then subjects who were below the median level were designated as having "low" activity intensity scores and subjects above the median were designated as having "high" activity intensity scores. A similar procedure was followed for activity frequency, where the PASE score was used as the outcome measure. There were 26 subjects who fell into the high frequency, high intensity group and 18 subjects who fell into the high frequency, low intensity group. A non-parametric t-test was used to compare the baseline fatigue severity scores between groups. The results did not provide support for our hypothesis. There was no significant difference in fatigue severity at baseline (p = 0.839) between these two groups. Future analysis will look at the daily fatigue ratings obtained from subjects during the week that they were wearing the step monitors. These fatigue ratings are recorded at the end of each day and may have a closer association to daily activity levels than the baseline measure.

Future data analysis will focus on pain severity and changes over time in the pain, fatigue and activity measures. New subjects are continuing to be recruited and we anticipate no problems in meeting the original study goals.

Study #2 Development of a Walking Model for Simulating the Effect of Localized Muscle Weakness

Administrative

- 1. One of the study Research Assistants (RAs), Thomas Coulter, was unable to fulfill his required commitment to the study for approximately 9 months. Mr. Coulter is a reservist in the National Guard and was activated in December 2002 to support Operation Enduring Freedom. His position was vacant for approximately 9 months. We were unable to identify a suitable replacement during this time. The other study RA, Mausam Patel, was able to contribute additional time to replace half of Mr. Coulter's hours. The remainder of his hours were not covered. Mr. Coulter has since returned from his mission and restarted in his original position as of September 29, 2003.
- 2. The computers required to develop, run, and test the simulation model were purchased as budgeted. Due to changes in RA operational structure, two computers were obtained. Reduction in computer costs allowed us to obtain the required resources for within the budgeted amount. Originally, it had been desired to have one full time RA. We were unable to find a single RA capable of that time commitment, but were able to find two half-time RAs instead. Since their hours were often coincident, 2 computers were necessary to allow both to work simultaneously. The computers were purchased in project year 2 rather than initially because the software (the model) was obtained late, and time to evaluate the model computational demands was required before making the best determination of computer requirements. After the software was obtained in May 2002, a temporary machine had been borrowed to evaluate computational demands of running the biomechanical model.

Scientific & Technical

1. An improved baseline was developed for the model.

The baseline was redefined as the resultant walking pattern and was found to be more realistic and thus a better approximation or representation of normal human walking. The primary improvements were reduction in exaggerated leg motions. This improved model performance was obtained during the initial evaluation and preparation for the sensitivity analysis. During that process, minor modifications were made to the model to gain familiarity with model performance and to determine how best to implement the sensitivity analysis. The understanding gained about the relationship between model performance and specific variables during this process facilitated this model improvement. The model consists of nearly 800 equations and nearly 200 variables, making the relationship between a single model parameter and model performance a complicated one. It is worth noting that fundamental model control structures were not

changed in order to gain the additional congruence of model and normal human walking noted above. Rather, the changes (improvements) were interpreted as more a fine-tuning. Thus, the stability and robust performance of the original model remain intact.

2. Model benchmarking

The model performance compared favorably to that tabulated in existing and laboratory (internal) normative human walking databases. Performing this assessment was also essential to familiarize the project staff with the model. A gait analysis report was generated detailing model performance. The model performance was fundamentally similar to normal human locomotion. Many parameters fall within published as well as our laboratory (i.e. internal) normative ranges. Some specific similarities and differences are now reported.

Temporospatial footfall parameters - a measure of gross walking performance - were reasonable for the model walking speed and anthropometrics. The vertical ground reaction forces (GRF) showed the familiar double humped shape as well as appropriate magnitudes. For a walking speed of 1.1m/s, the noted peak GRF greater than body weight was appropriate. During midstance, the body accelerates downward resulting in a GRF less than body weight. This was also reproduced in the model. The loading rate of the leg from heelstrike to footflat was slightly higher than observed in normal human barefoot or shod walking. Progression of the center of pressure under the foot during stance phase was qualitatively similar to that seen in human walking. The timing of muscle activation corresponded reasonably well. The overall phases and range of motions of the joints were also strongly similar. One exception is that of the hip and knee, both of which showed excessive flexion during swing phase. The stance phase knee also showed noticeably less flexion during the loading phase. The joint kinetics showed qualitative similarities to published and internal data, but noticeably more differences than the kinematic data. These data were more difficult to quantitatively compare to normative ranges due to unavailability of published age, gender and speed matched joint moment data. Further model assessment and evaluation along the lines detailed above will be reported in the IDA or acceleration based analysis.

3. Sensitivity analysis and interpretation has been completed (see Appendix III)

The model was found to not be overly sensitive to any one group of parameters and thus is suitable for the simulation of muscle weakness and compensatory response without any further modification. It was necessary to determine the robustness of the model performance as our group did not have prior operational experience with this specific model; regardless, these data had not been published in sufficient detail in previous literature describing this type of model. Thus, it was a necessary analysis to be run before simulating muscle weakness and evaluating the compensatory process. More detailed results and how the sensitivity analysis was run follow.

The model demonstrated stability of performance over a wide range of changes in each parameter group. Changes are reported in terms of percent difference from the baseline condition. The model was capable of producing stable locomotion over a range of changes from 70 to 182% in the sensory group. Similarly, the neural group could be

changed from 56-145%, the posture control group from 87-170%, and the movement generator group from 90-120%. An overview of sensitivity analysis methodology follows.

Five groups of parameters from four major subsystems of the model were identified from the nearly one hundred parameters and variables used in the model. The parameters in the neural interconnectivity, sensory feedback, posture control, and movement generator subsystems were selected. The final parameter was the "nonspecific input" – thought to be related to an integrated higher level (brain) parameter. The range of values of these parameters for which the model could perform the walking task successfully was determined by incrementally varying each group of parameters in approximately 5% intervals while all the other parameters were held constant.

4. Intersegmental Dynamics Analysis (IDA) based analysis

Codes to access and rearrange Adams data formats to allow running of batch simulations
to calculate IDA have been written and tested. IDA or induced acceleration analysis is
the method to objectively and quantitatively calculate the effect of a single muscle force
or net joint moment on body kinematics (acceleration). These codes were based on a
different format from those previously developed in our lab (written in Matlab) that
calculated accelerations directly from loads applied to the body because Adams does not
calculate accelerations directly. Assessing the accuracy of IDA results was done in a
manner similar to how it was originally done in our lab. The regenerated ground reaction
forces (GRFs), joint accelerations, and pelvis forward accelerations were compared to the
originally measured values.

Results of the initial IDA assessment of model performance showed that the model reproduces the vertical GRF in a manner similar, though not yet quantified, to that of a normal human during walking. Previous IDA analysis run in our lab was used to compare to the model breakdowns. These data could only be compared to internal or laboratory databases as these data have not been published in literature. Interpretation of the IDA analysis gave insight into the functional relationships between model muscle activation and model walking performance. This analysis also served as additional support to the similarity of the model control scheme to that of a normal human during undisturbed walking. Reconstruction of additional body degrees of freedom, such as joint rotation and pelvis translation, will further validate the IDA implementation and further support model similarity to human performance. This work will also lead directly to the calculation of the functional deficits database, as originally outlined. These IDA based analyses are still underway.

5. Perturbation analysis and interpretation have been partially completed

The ability of the model to respond in a realistic manner to a limited variety of perturbations suggests the appropriateness of the model for studying the effect of muscular weakness during a walking task. Responses were consistent with that expected based on knowledge of muscle roles during gait, interpretation of acceleration analyses, and anecdotal clinical cases. The model response to individual muscle weakness and to

major subsystem perturbation (sensitivity analysis) was interpreted with a perspective of characterizing the quality of the response compared to a human. The following is a brief overview of the preliminary interpretation of these analyses: The hip extensor weakness resulted initially in an increased step length. As the model appeared to be heading towards instability and collapse, it was able to rectify the instability and produce a shorter step length - more consistent with a learned response of an individual with hip extensor weakness. The contribution of the late stance/early swing knee flexor torque to braking of body forward propulsion was increased with knee extensor weakness. The knee extensor weakness resulted in an increased flexor torque. Surprisingly, there was little stance phase effect of weakened knee extensors. The ankle plantarflexor weakness results have not been fully understood yet. This work is in progress. Hip, knee and plantarflexor muscle weaknesses were modeled by reducing the rhythmic force coefficient. The resultant joint torques (hip, knee and ankle) were verified to be reduced. The responses of the model from the sensitivity analyses were also generally consistent with those that may be expected from qualitatively similar physiological situations, thus further supporting the appropriateness of the model response. Once the determination of model appropriateness has been made, a few normal subjects will be tested in order to compare to the model. Subject recruitment and testing, as defined in the human subject testing section of the protocol, is expected to begin in approximately 6 months.

KEY RESEARCH ACCOMPLISHMENTS:

- A total of 43 polio survivors and 63 controls have been enrolled in Study 1.
- Preliminary data analysis in Study #1 has begun.
- An improved baseline has been developed for the simulation model in Study #2.
- Sensitivity analysis of the model has been completed.
- Initial IDA assessment of model performance has been performed.
- Perturbation analysis and interpretation are underway.

REPORTABLE OUTCOMES:

- Talaty M, Patel M, Coulter T, Esquenazi A, Klein M. Physics-based Computer Simulation to Assist in the Understanding of Mobility Dysfunction and Rehabilitation. [Oral Presentation] Research in Progress Symposium, MossRehab Hospital, Philadelphia PA, September 2003.
- Talaty M, Patel M, Esquenazi A, Klein M. The Effect of Variation of Neuromusculoskeletal Model Control Parameters on Performance During Simulated Human Walking. [Paper Presentation] International Society of Biomechanics meeting, Sydney, Australia, July 2003.

- Patel M, Talaty M, Klein M, Esquenazi A. Evaluation of a Computer Model to Simulate Human Walking and Understand Compensatory Behavior for Muscle Weakness. [Poster Presentation] Research Recognition Day, Albert Einstein Medical Center, Philadelphia PA, May 2003.
- Patel M, Coulter T, Talaty M, Esquenazi A, Klein M. Development Of A Computer Model
 To Simulate The Effect Of Localized Muscle Weakness On Walking. [Poster Presentation]
 Annual Meeting of the Gait and Clinical Movement Analysis Society, Wilmington DE, May
 2003.

CONCLUSIONS:

This section is not applicable at this time.

APPENDIX I

Analysis of Activity Patterns and Performance in Polio Survivors: An Analysis of Health Status and Activity Level in Polio Survivors Over Time

Inclusion Criteria

- Polio Survivor reporting new or worsening muscle weakness possibly due to late effects of polio
- Adult over age 45 with no history of polio but reporting some difficulty with mobility related tasks like walking or climbing stairs
- Must be able to ambulate a minimum of 3 feet with or without the use of an assistive device on a level surface
- Must be able to attend two study visits at the research office

Exclusion Criteria

- Kidney Failure needing dialysis
- Rheumatoid Arthritis
- Diabetes requiring medication for control
- Stroke (with sequelae)
- Cancer (other than skin) with current treatment
- Uncontrolled Seizures
- Uncontrolled High Blood Pressure
- Any cardiac or respiratory conditions that are not controlled
- Recent bone fracture (last 6 months)
- Spinal disc herniation or other back/neck disorders with new or worsening symptoms
- Polymyalgia rheumatica, systemic lupus erythematosus (SLE), muscular dystrophy, multiple sclerosis or similar conditions
- Any neuromuscular disorder (other than polio) such as Parkinson's disease
- Severe deformity or acute pain/swelling that would make doing the study tasks unsafe
- Any problem that makes it difficult to understand what is involved in the study or that may affect desire to perform the study tasks or that may make if difficult to do the study tasks
- Dementia or psychiatric illness

Determining Eligibility

Potential subjects are initially screened through a phone conversation during which subjects are asked to respond to a series of questions about medical conditions, polio history if applicable, and ability to do certain mobility related tasks. The questions asked are designed to elicit information specifically related to the inclusion and exclusion criteria identified in the informed consent form. This initial screening is reviewed to identify eligibility.

If exclusions are not identified and inclusion criteria are met, a subject history form (which includes medical history), and a polio history form are mailed to the subject for review and completion.

At the first visit, a research team member reviews the subject history and polio history forms completed by the subject to identify if any new information is provided that may impact eligibility.

| Date: Scheduled | for: |
|---|---------------|
| Meets/Does not meet criteria. (wants to stay in Dbase?Yes No) Packet | t sent on: |
| DATE SCREENED | |
| SCREENING QUESTIONNAIRE [ACTIVITY MONI | (TOR) |
| | |
| NAME: | D.O.B: |
| STREET:CITY: | AGE: |
| PHONE | |
| HOW DID YOU HEAR ABOUT THE STUDY: | , |
| 4 MANTENOLINAD DOLLO | X/ |
| HAVE YOU HAD POLIO? AT WHAT AGE? | Y es No |
| WHERE (WHAT BODY AREA) DID IT AFFECT YOU? | |
| • | |
| 2. HAVE YOU EVER BEEN TOLD YOU HAVE PPS? | YesNo |
| 3. ARE YOU EXPERIENCING ANY NEW SYMPTOMS THAT MAY I | RE RELATED TO |
| PPS? (for instance, increasing weakness or fatigue) | |
| | · · |
| How long have you had the symptoms? | |
| 4. DO YOU HAVE ANY OF THE FOLLOWING? | |
| A. DIABETES | YesNo |
| IF YES, DO YOU TAKE INSULIN OR A PILL? | |
| B. ARM WEAKNESS THAT MAKES YOU UNABLE TO | , |
| USE YOUR ARMS TO GET OUT OF A CHAIR? | Yes No |
| | |
| C. ANY DISEASE THAT CAUSES JOINT INFLAMMATION?- | Yes No |
| FOR EXAMPLE, RHEUMATOID ARTHRITIS | |
| D. ANY DISORDER SUCH AS | |
| FIBROMYALGIA | |
| SEIZURES | |
| PARKINSON'S DISEASE? | |
| MUSCULAR DYSTROPHY? | |
| LUPUS (SYSTEMIC LUPUS ERYTHEMATOSUS)? MULTIPLE SCLEROSIS? | |
| POLYMYALGIA RHEUMATICA? | |
| HIGH BLOOD PRESSURE? | |
| Do you take medication for your blood pressure? | |
| 20 you take medication for your blood pressure: | 101 |

| Date: | Name: | | |
|----------|---|----------|---------|
| . | E. A HEART CONDITION THAT IS NOT CONTROLLED? | Yes | |
| | DO YOU SUFFER FROM CHEST PAIN AT REST? | | |
| | HAVE YOU EVER HAD A HEART ATTACK ?WHEN? | | |
| | DO YOU HAVE A PACEMAKER OR OTHER IMPLAI Yes No | NTED D | EVICE? |
| | F. A BREATHING CONDITION THAT IS NOT CONTROLLED? | Yes | No |
| | DO YOU USE OXYGEN? | - Yes | No |
| | G. ANY PROBLEMS WITH YOUR BACK OR NECK? | - Yes | No |
| | • WHERE? | | |
| | DO YOU KNOW IF YOU HAVE ANY HERNIATED DISC | CS? | |
| | YesNo | | |
| | WHERE? | | |
| | | | |
| | PLEASE DESCRIBE THE PROBLEM | | |
| | HOW/WHEN WAS IT DIAGNOSED? | | |
| • | HAVE YOUR SYMPTOMS GONE AWAY? | -Yes | _ No |
| | WHAT SYMPTOMS ARE YOU HAVING? (Any radiating pain in arms or legs? Any numbness or tire | ngling?) | · |
| | ARE THE SYMPTOMS GETTING BETTER, REMAINING DO THEY SEEM TO BE GETTING WORSE? | 3 THE S | AME, OF |
| | | | |
| I | I. CANCER THAT YOU ARE BEING TREATED FOR? | Yes | No |
| . HAV | E YOU HAD: | | |
| A | SURGERY IN THE LAST 6 MONTHS?FOR WHAT / WHERE? | -Yes | No |

| Date: | Name: | | |
|-----------------|---|------|-------------|
| | BROKEN BONES OR DISLOCATIONS IN THE LAST | Yes | No |
| | WHERE? | | |
| | | | |
| C. A ST | ROKE? | Yes | No |
| 5. CAN YOU | STAND UP FROM A CHAIR? | Yes_ | No |
| 6. CAN YOU V | VALK? | Ves | No |
| | UT HOW FAR? | 105 | |
| • DO Y | OU USE A DEVICE TO HELP? | Yes | No |
| | What kind? | | |
| | ou wear an ankle or knee support of any kind? Please describe. When do you wear it? When was the last time that you used | | side?) |
| • DO Y | OU WEAR BRACES? | Yes | No |
| | WHAT KIND? | | |
| | WHEN? | | |
| 7. DO YOU HA | AVE ANY LIMB DEFORMITIES OR AMPUTATIONS (NO | T! | |
| RELATED TO | O POLIO)? | -Yes | No |
| | | | |
| 8. DO YOU HA | AVE ANY AREA OF SEVERE PAIN OR SWELLING? | Yes | No |
| | S THIS AREA MAKE IT SO YOU ARE UNABLE TO DO | | |
| YOU | R NORMAL TASKS? | Yes | No |
| 9. DO YOU HA | AVE KIDNEY FAILURE OR RECEIVE DIALYSIS? | Yes_ | No |
| 10. HAVE YOU | EVER BEEN TOLD YOU HAVE A MENTAL ILLNESS | | |
| | EPRESSION, SCHIZOPHRENIA, BIPOLAR DISORDER, O | | |
| ANXIETY?- | | Yes | No |
| 11 DO VOILHA | VE ANY PROBLEM THAT WOULD MAKE IT DIFFICUL | т | |
| | O FOLLOW WRITTEN OR SPOKEN DIRECTIONS? | | No |
| 10101001 | or obbott with the or of orbit birds of orbit. | 103 | |
| | | | |
| | | | |
| PLEASE BATE | YOUR ABILITY TO DO THE FOLLOWING ON A SCA | IFOF | |
| | (UNABLE TO DO) TO 4 (NOT DIFFICULT): | | , |
| | | • , | |
| | | RAT | NG |
| 1. WALK A 1/4 (| OFA MILE (3-4 City blocks) | KAII | LINO |
| | , | | |
| 2. GO UP A FL | IGHT OF STAIRS | | · . |
| 3 STOOP DOV | VN (hending) | | |

| Da | ite: | ime: | | | |
|------------|--|-----------------|-----------|------------|----|
| 4 . | CROUCH (like a catcher in a baseball game) | | | | ٠ |
| 5. | KNEEL DOWN | | | | |
| 6. | PUSH A LARGE OBJECT (such as a bed or s | sofa) | | | |
| 7. | CARRY 10LBS (across the room) | | | · . | |
| 8. | BATHE | | | · <u></u> | |
| 9. | DRESS | | | | |
| 10 | LIFT AND CARRY GROCERIES | | | | |
| | | | | | |
| | | | | | , |
| • | DO YOU HAVE ANY ALLERGIES? | | Yes | No | |
| | IF YES, PLEASE EXPLAIN? | | | | |
| | | | | | |
| • | ARE YOU ALLERGIC TO LATEX? | | Yes | | |
| | IF YES, DESCRIBE REACTION | | | | |
| | | | | | |
| | | | | | |
| • | ARE YOU PARTICIPATING IN ANY OTHE PROGRAM? IF YES, DESCRIBE. | ER RESEARCH OF | R TREATMI | ENT | |
| | | | | | |
| • | IS IT OKAY FOR US TO LEAVE A MESSA SAYING THAT WE ARE CALLING FROM OFFICE? | | | | [|
| • | ARE YOU AN EMPLOYEE OF THE JEFFEI | RSON/EINSTEIN I | HEALTH CA | ARE SYSTEM | 1? |
| • | WHEN IS THE BEST TIME FOR US TO CA | LL YOU? | | | |
| | | | | | |

APPENDIX II

| • | | |
|---------|-----------|--|
| Subject | Initials: | |

| Subject | ID: |
|---------|-----|

Subject History

| • | Date of Birth: | Sex: MF | Race: | |
|-----|--------------------------------|---|--------------------|---------------------------------------|
| | Are you a veteran? Yes | No .? Rt Lt Both | | |
| • . | | o you step forward with first? | | Both |
| | Wildi Walking, Wildi 1880 a. | 5 y 0 4 0 0 0 p 10 2 11 0 2 2 11 11 2 11 2 11 2 | | |
| • | List Allergies to Medication, | and the type of reaction you ha | ve if you know: _ | |
| | | | | |
| | List all medications you are t | aking (including over-the-coun | ter and herbal med | licines), the |
| • | dose and the frequency: | aning (morading ever the count | | , |
| | • | REASON FOR TAKING | DOSE / FI | REQUENCY |
| | | | | |
| 4 | · | | | |
| | | | | |
| | | | | · · · · · · · · · · · · · · · · · · · |
| | | | | <u></u> |
| | | | | |
| | | | | |
| | | | | |
| | Have you been discussed on | treated for any of the following | conditions: | |
| • | Heart problem | Osteoporosis | Asthma | |
| | Angina | Osteoporosis Arthritis | Emphysema | |
| | High blood pressure | Thyroid | COPD | |
| | Cholesterol | Cancer | Glaucoma | |
| | Cholostoloi | Canoon | Giauconia | |

| • | | |
|---------|-----------|--|
| Subject | Initials: | |

Subject ID:

Please list any other medical conditions you are aware you have, and when you learned of · the condition.

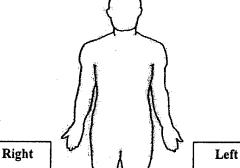
• List all surgeries that you have had and the approximate date.

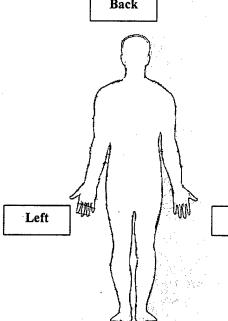
1._____4.____

2. _____ 5. 3. _____6.

- List all broken bones that you have had. Please include how the bone was broken and when.
- If you are a woman, have you gone through menopause? Yes No
 - If yes, are you taking hormone replacements? Yes____ No____
- On the 'body' below, please shade in any areas that you feel pain or discomfort on a regular

basis.





Right

^{*}For the areas that you marked, are you taking any medication? Yes____ No___

| Subject Initials: | | Subject ID: |
|--|--|-------------|
| • Do you smoke? Yes No_ | | |
| • If yes, what is the average | number of packs you smoke in a week? | |
| • Do you care for someone on a | regular basis (such as a child or dependent adult) |) ? |
| YesNo | | |
| • If yes, how often? | | |
| • Do you help another person(s) | with his or her daily activities? Yes No | |
| What things do you help wi | ith? | |
| • On average, how many hou | rs per week do you help? | |
| Does anyone help you with you | ur daily activities? Yes No | |
| What things if any, do you need | ed help with? | |
| Does someone help you with ir | ndoor household chores? Yes No | , |
| • Does someone help you with o | outdoor household chores? Yes No | |
| • Do you receive pay for work? | Yes No | • |
| • | g: Full time (30-40hrs/week) | |
| | Part-time(less than 30 hrs/week) | |
| | Not working for pay | · |
| What type of work do you | ou do? | |
| Do you do volunteer work? Ye | es No | |
| | number of hours you volunteer in a month? | |
| | vities do you do? | |
| De voes essential 1 ' 0.37 | NT- | |
| • Do you currently drive? Yes | | |
| Do you use / wear eyegiasses of Are you able to read newspa | or contact lenses? YesNo | · |

| Subject Initials: | Subject ID: |
|---|---------------------------------------|
| Do you have any trouble hearing? Yes No | |
| Do you use a hearing aid? Yes No | |
| • Which ear? Lt Rt Both | |
| | |
| Have you fallen in the last year? Yes No | |
| • If yes, about how many times? | |
| Were you injured? Yes No | |
| Describe the injury. | |
| Describe the injury. | · · · · · · · · · · · · · · · · · · · |
| Have you had any trouble with dissipant in the last years Xan Na | |
| Have you had any trouble with dizziness in the last year? Yes No 1 Contact the last year? Yes No | - |
| If yes, please explain (how often, when etc) | · . |
| | |
| | |
| • Please rate the quality of your sleep in the last 2 weeks: | |
| very restfulsomewhat restfula little restfulno | t restful at all |
| How does this compare with your usual sleeping pattern? | |
| less restful than usualabout the samebetter than usual | |
| | |
| • Please rate your stress level in the last 2 weeks: | |
| not very high somewhat highhighver | y high |
| How does this compare with your normal stress level? | |
| lower than normalabout the samehigher than no | ormal |
| | |
| | |
| • What is your current marital status? | |
| • | |
| SingleMarried | |
| | |

| Su | bject Initials: | Subject ID: |
|----|---|---------------------|
| • | What is your current living arrangement? | |
| | Live alone Live with friend(s) | |
| | Live w/family member(s) Other | |
| | How many people live in your household? | |
| | | |
| + | Do you have a pet(s)? Yes No | |
| | What kind of pet(s) do you have? | V 4 |
| | Who takes care of the pet(s)? | |
| | 1 (/ | |
| • | What is your highest level of education? | |
| | Less than high school graduate | |
| | High school graduate or equivalent | |
| | Some college education | |
| | Completed college degree | |
| | | |
| • | When you walk, do you use an assistive device? Yes No | |
| | • If yes, what kind? | |
| | When do you use the device? | |
| | AlwaysInside homeOutside homeI | Long distances only |
| | | |
| • | Can you rise from a chair without using your arms for assistance? Yes | No |
| | | |
| • | Can you go up a flight of stairs without using a handrail? YesNo | |
| | Can you go up a flight of stairs using a handrail? Yes No | |
| | | |
| • | Can you go down a flight of stairs without using a handrail? Yes1 | No |
| • | Can you go down a flight of stairs using a handrail? Yes No | |
| | | - |

- 1. At what age did you have polio? _____
- 2. Which type of polio did you have?

Bulbar

Spinal _____

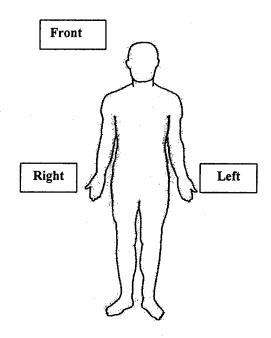
Both _____

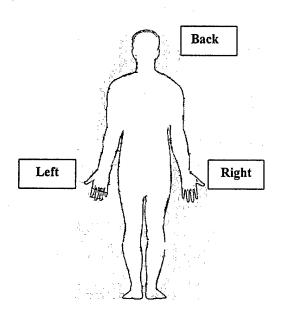
Unsure

- 3. Did you have to use an iron lung? Yes ____ No ___
- 4. On a scale of 0 10, please rate how severely you were initially affected by polio. ('0' is no affect; '10' is severely affected)

RATING:

5. Please shade on the 'body' below where you were affected.





6. Do you wear braces now? Yes ___ No ___ If yes, how many hours each day? ____

What type of braces? Rt short leg ____ Lt short leg ____ Back ____ Other ____

Rt long leg ___ Lt long leg ___ Neck

7. Do the braces lock at the knee? RT: yes___ no___ n/a ___

LT: yes___ no__ n/a ___

8. When did you start wearing braces?

| Do you have an insert or special | shoe to co | rrect a | leg length | discrep | ancy? Yes | No |
|---|---------------|---------|------------|----------|--------------|--------------|
| If Yes: Left Right _ | | | | | | |
| 0. Do you use any devices such as | : Cane: | yes | no | Whee | lchair: yes | s no |
| | Crutches: | yes | no | Sc | cooter: yes | no |
| | Walker: | yes | no | | Other: yes | s no |
| | | | | | | |
| • If you use a cane, which ha | and do you | use it | with? | Left | Right | Both |
| • If you use crutches, which | arms do yo | ou use | them with? | Left | Right | Both |
| If you use a wheelchair or (always, distance walki | - | | • | | | |
| | | | | | | |
| weakness or fatigue?) No Y If yes, what symptoms are you | | | | | | |
| How many years passed from the experienced symptoms of Post I | - | | _ | o to the | e time you f | īrst |
| Up to 5 years | | |] | Not hav | ving any sy | mptoms |
| More than 5 year | rs, but less | than | 10 years | | | |
| More than 10 year | ars, but less | than | 15 years | | | |
| More than 15 year | ars, but less | than? | 20 years | | | |
| Mana Alaan 20 aan | | | | | | |
| More than 20 year | ars | | | | | |
| | | | • | | | |
| .On a scale of 0 – 10, please rate h | ow severel | y you | • | y affec | cted from po | olio symptom |
| .On a scale of 0 – 10, please rate h ('0' is no affect; '10' is severely a | ow severel | y you | • | y affec | cted from po | olio symptom |

Page 2 of 4

Since the onset of Post Polio Syndrome (PPS), have any of the following health problems been experienced?

If yes, circle a number from 1-10 that indicates how severe the problem is for you (1 is very mild; 10 is very severe)

| | | | | SI | EVE | RIT | ΥR | ATI | NG | | |
|---|-----|---|--------------|--------------|-----|--------------|----------|----------|----------|----------|------------|
| New weakness in 'affected' muscles • Location: | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| New weakness in 'unaffected' muscles | | ļ | | | | | ļ | | <u> </u> | <u> </u> | |
| new weakliess in unaffected indiscres | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| • Location: | 110 | 1 | ~ | | 7 | | | ′ | 0 | | 10 |
| Tiredness in 'affected' muscles | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| • Location: | | | | ļ | | ļ | | | | ļ | ļ |
| Tiredness in 'unaffected' muscles | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| • Location: | | | | | | <u> </u> | | | | | |
| Muscle twitching in 'affected' muscles • Location: | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| | | | <u> </u> | | | <u> </u> | | | <u> </u> | - | ļ |
| Muscle twitching in 'unaffected' muscles | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| • Location: | | | ļ | ļ | | | | | | | ļ <u>.</u> |
| Muscle cramping in 'affected' muscles | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9. | 10 |
| • Location: | | | | | | | <u> </u> | | , | | ļ <u>.</u> |
| Muscle cramping in 'unaffected' muscles | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| • Location: | | - | ~ | | ' | | | ' | | | 10 |
| Pain in 'affected' muscles | | | | | | | | | | | |
| • Location: | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Pain in 'unaffected' muscles | 710 | | | | | _ | | | | | 1.0 |
| • Location: | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Since the onset of Post Polio Syndrome (PPS), have any of the following health problems been experienced?

If yes, circle a number from 1-10 that indicates how severe the problem is for you (1 is very mild; 10 is very severe)

| | | | | SE | EVE. | RIT | Y R | ATI | NG | , | |
|---|----|---|---|----|------|-----|-----|-----|----|---|----|
| Change in size of 'affected' muscles • Location: | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Change in size of 'unaffected' muscles • Location: | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Breathing difficulty | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Problems concentrating | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Swallowing problems | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Sleeping problems | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 · | 8 | 9 | 10 |
| Depression | NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

| Subject Initials: | Date: |
|-------------------|----------|
| Subject ID: | Visit #: |

FATIGUE SCALE

FATIGUE SEVERITY SCALE QUESTIONNAIRE

| DI | DURING THE PAST WEEK, I found that: | | ngly igree | | | . | Strongly Agree | | |
|----|--|---|---------------|---|---|----------|-------------------|---|--|
| 1. | My motivation is lower when I am fatigued. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 2. | Exercise brings on my fatigue | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 3. | I am easily fatigued | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 4. | Fatigue interferes with my physical functioning | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 5. | Fatigue causes frequent problems for me | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 6. | My fatigue prevents sustained physical functioning | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 7. | Fatigue interferes with carrying out certain duties and responsibilities | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 8. | Fatigue is among my three most disabling symptoms | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 9. | Fatigue interferes with my work, family, or social life | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |

| SUBJECT ID: | SUBJECT INITIALS: | DATE: | |
|-------------|-------------------|--------|---|
| • | | VISIT: | · |

SICKNESS IMPACT PROFILE (SIP 68)

Directions (Please Read Thoroughly):

Daily life consists of a number of activities. Sometimes you can carry out all of these activities. It is possible, however, that you don't do a number of these activities in the usual way as a result of your health or physical limitations. You may have stopped doing some activities altogether, you may do the activities differently, or you may do the activities for a shorter period of time. We are interested in the types of changes in your activities that are related to your state of health. These changes may have occurred only recently, or they may have taken place some time ago.

Read the statements one by one and determine if they are applicable to your situation today. Also determine if they apply to you because of your state of health. If this is the case, mark an X in front of the statement and go on to the next one. For example, one of the statements is:

___ I stay home most of the time.

If this statement is true and related to your state of health, mark an X in front of it.

X I stay home most of the time.

You mark an X even if you have stayed home as a result of your state of health for a longer period of time. Don't mark an X if you're spending most of your time at home because you want to read a book, or because the weather is bad. In this case you are at home a lot because of the weather or because you want to read a book, not because of your health. You should mark an X next to statements that concern changes that have occurred recently or some time ago.

In short, mark an X next to statements that:

- · Describe your SITUATION TODAY
- · Are true as A RESULT OF YOUR HEALTH

Please do not consult others on any of the statements. We are interested in what you think.

You may begin filling out the questionnaire. Read the statements carefully and determine if they describe your situation and if they are related to your state of health.

Sickness Impact Profile (shortened version)

A. F. de Bruin, J.P.M. Diedericks, L.P. de Witte, F.C.J. Stevens, H. Philipsen

©IRV Hoensbroek and © Faculty of Medical Sociology of the University of Limbury, Maastricht, The Netherlands

- Describe your **SITUATION TODAY**
- · Are true as A RESULT OF YOUR HEALTH

| 1 | I get around in a wheelchair. |
|----|---|
| 2 | I get dressed only with someone's help. |
| 3 | I do not move into or out of bed by myself. I am moved by |
| | another person or technical aid. |
| 4 | I stand up only with the help of another person. |
| 5 | I do not fasten my clothing (for example, requiring help with buttons |
| | zippers, shoelaces) |
| 6 | I do not walk at all. |
| 7 | I do not use stairs at all. |
| 8 | I make difficult moves with help (for example, getting into or out |
| | of cars or the bathtub). |
| 9 | I require assistance with some portions of bathing. |
| 10 | I do not bathe myself completely (for example, requiring assistance |
| | with bathing) |
| 11 | I do not have control of my bladder. |
| 12 | I am very clumsy in body movements. |
| 13 | I do not have control of my bowels. |
| 14 | I feed myself with help from someone else. |
| 15 | I do not maintain balance. |
| 16 | I use a bedpan with assistance. |
| 17 | I am in a restricted position all of the time. |

| SUBJECT ID: | SUBJECT INITIALS: | DATE: |
|-------------|-------------------|--------|
| OODIDOI ID. | BOBJECT HATTHES. | |
| | | VISIT. |
| | | |

- Describe your SITUATION TODAY
 Are true as A RESULT OF YOUR HEALTH

| 1 | I go up and down stairs more slowly (for example, one step at a time or |
|----|---|
| | stopping often). |
| 2 | I walk shorter distances or stop to rest often. |
| 3 | I walk more slowly. |
| 4 | I use stairs only with mechanical support (for example, a handrail, a |
| | cane or crutches). |
| 5 | I walk by myself but with some difficulty (for example, limping, |
| | wobbling, stumbling, with stiff legs). |
| 6 | I kneel, stoop, and bend down only by holding onto something. |
| 7 | I do not walk up or down hills. |
| 8 | I get in and out of bed and chairs by grasping something for support or |
| | by using a cane or walker. |
| 9 | I stand only for short periods of time. |
| 10 | I dress myself, but do so very slowly. |
| 11 | I have difficulty doing handwork (for example, turning faucets, using |
| | kitchen gadgets, sewing, carpentry). |
| 12 | I move my hands or fingers with some limitation or difficulty. |

- Describe your SITUATION TODAY
 Are true as A RESULT OF YOUR HEALTH

| 1 | I have difficulty reasoning and solving problems (for example, |
|-----|--|
| | making plans, making decisions, learning new things). |
| 2 | I have difficulty doing activities involving concentration or thinking. |
| 3 | I react slowly to things that are said or done. |
| 4 | I make more mistakes than usual. |
| 5 | I do not keep my attention on an activity for long. |
| 6 | I forget a lot (for example, things that happened recently, where you pro- |
| | things, appointments). |
| 7 | I am confused and start several activities at the same time. |
| 8 | I do not speak clearly when I am under stress. |
| 9 | I have difficulty speaking (for example, getting stuck, stuttering, |
| | stammering, slurring words). |
| 10 | I do not finish the things I start. |
| 1 1 | I have trouble writing or typing |

| SUBJECT ID: | SUBJECT INITIALS: | DATE: |
|---|---------------------|--------|
| , o b o b o b o b o b o b o b o b o b o | 0020201 11011111201 | |
| • | | VISIT: |

- Describe your SITUATION TODAY
 Are true as A RESULT OF YOUR HEALTH

| 1 | I am cutting down the length of my visits with friends. |
|------|--|
| 2 I | am drinking less fluids. |
| 3 I | am doing fewer community activities |
| 4 I | am doing fewer social activities with groups of people. |
| 5I | am going out for entertainment less often. |
| 6 I | stay away from home only for brief periods of time. |
| 7 I | am eating much less than usual. |
| 8 I | am not doing heavy work around the house. |
| 9 I | do my hobbies and recreational activities for shorter periods of time. |
| 10 I | am doing less of the regular daily work around the house than I would. |
| 11 I | am cutting down on some of my usual inactive recreational activities |
| | and nastimes (for example watching TV playing cards reading) |

| SUBJECT ID: | SUBJECT INITIALS: | DATE: |
|-------------|-------------------|--------|
| • | | VISIT: |

- Describe your SITUATION TODAY
 Are true as A RESULT OF YOUR HEALTH

| I. | 1 often act irritable towards those around me (for example, snapping at |
|----|---|
| | people, giving sharp answers, criticizing easily). |
| 2. | I act disagreeable with my family members (for example, acting |
| | spiteful or stubborn). |
| 3. | I have frequent outbursts of anger at family members (for example, |
| | striking at them, screaming, throwing things at them). |
| 4. | I act irritable and impatient with myself (for example, talking badly |
| | about yourself, swearing at yourself, blaming yourself for things that |
| | happen). |
| 5. | I am not joking with family members as I usually do. |
| 6. | I talk less with those around me. |

| SUBJECT ID: | SUBJECT INITIALS: | DATE: |
|-------------|-------------------|--------|
| | | VISIT: |

- Describe your SITUATION TODAY
 Are true as A RESULT OF YOUR HEALTH

| 1 | I am not doing any of the shopping that I would usually do. |
|----|---|
| 2 | I am not going into town. |
| 3 | I am not doing any of the house cleaning that I would usually do. |
| 4 | I am not doing any of the regular work around the house that I would |
| | normally do. |
| 5 | I stay home most of the time. |
| 6 | I am not doing any of the laundry that I would usually do. |
| 7 | I am not going out to visit people at all. |
| 8 | I am getting around only within one building. |
| 9 | I have given up taking care of personal or household business affairs |
| | (for example, paying bills, banking, working on a budget). |
| 10 | I do not get around in the dark or in unlit places without someone's |
| | help. |

| Subject ID: | | | H | Tester Initials: | | | | Date: | | | • |
|--|------------------------------|-----------------------|---------------|------------------|---------------|--------------------|----------------------------|---------------|------------|------------------|-----|
| Subject Initials: | | | | , | | | | Visit | | • | . • |
| | Height: | We | Weight: | | | Monitor ID Number: | umber: | | | | |
| STRENGTH EVALUATION: | VALUATIO | Ž | | · | | Cadence Setting: | Setting: | | | | |
| | | | LEFT | | | | | RIGHT | | | : |
| | | DYNAMOMETER RESULT | OMETER ULT | | MANUAL | | DYNAMOMETER RESULT | OMETER ULT | | MANUAL | |
| | TRIAL 1 | TRIAL 2 | TRIAL 3 | TRIAL 4 | MUSCLE RESULT | TRIAL 1 | TRIAL 2 | TRIAL 3 | TRIAL 4 | MUSCLE RESULT | |
| KNEE | | | | | | | | | | | |
| MOBILITY EVALUATION: | /ALUATION | اخ ا | | | | ACTI | ACTIVITY MONITOR SETTINGS: | TOR SETT | NGS: | | |
| First forward step taken with | ep taken witł | q | _ foot | | | 1. Qu | 1. Quick stepping: | Yes | No | | |
| Assistive de | Assistive device use: No | Yes Type:_ |)e: | | | | | | | | |
| | | II | | # of Steps Taken | en | | Walking Speed: Normal | : Normal | Fast | Slow | * |
| 1. Walk 30 Feet at Max Speed | t at Max Spe | pec | , | | | 3. Ra | Range: Both | Both extremes | Mod range | mge | |
| 2. Walk 30 Fee | Walk 30 Feet at Normal Speed | Speed | | | | | | Rarely varies | aries | | |
| STEP LENGTH: (30ft / # of steps) | H:s | | | | | 4. Leg | 4. Leg motion: Fidgety | | Norm Ge | Gentle | |
| BODY MASS INDEX: (wt in kg / ht in meters squared) | INDEX: meters squar | red) | | | | *Tim | *Time Monitor Applied: | Applied: | | | |

| Subject ID: | Subject | t Initials: | Date: | Visit: |
|----------------|--|-------------------------|-----------------------|--------------|
| IN THE | E LAST 3 MONTHS | | | |
| 1. Have | e you: | | | |
| | Had any health probles Received treatment fro | | yes no yes no | |
| | Had any medical tests? | | yes no | |
| | Had your medications Been hospitalized? | cnanged? | yes no yes no | |
| | Been Injured? | | yes no | |
| - F | Fallen? | | yes no | |
| • A | your activity level chare you doing more? you hat is it that you are o | es no | - | |
| COMPA | ARED TO 3 MONTH | S AGO: | | |
| | would you rate your | - | - | rities? |
| a. | When working (at a | | | |
| | Accomplish Less | Accomplish the San | ne Accomplish | More |
| b. | When doing leisure | activities (at home or | in social situations) | |
| | Accomplish Less | Accomplish the San | ne Accomplish | More |
| 4. Are y | you able to do more no | ow? | | |
| a. | When working (at a | job or volunteering): | | |
| | | No change | No, able to do le | ess |
| b. | When doing leisure | activities (at home or | in social situations) | |
| | _ | No change | · · | ess |
| 5. When | n completing your nor | mal daily activities, h | now would you rate th | ne length of |
| time | it takes? | | | |
| a. | When working (at a | job or volunteering): | | |
| | More Time | Same Amount of Tin | ne Less Tin | ne |
| b. | When doing leisure a | activities (at home or | in social situations) | |
| | More Time | Same Amount of Tin | • | ne |

| Subject ID: | Subjec | t Initials: | | Date: | Visit: |
|----------------|---|-------------|------------------|----------------|---------------------------------|
| COMPA | ARED TO 3 MONTH | S AGO: | | | |
| 6. Does | s it take less effort to o | omplete y | our normal da | ily activities | ? |
| a. | When working (at a | job or vol | lunteering): | | |
| | Yes, less effort neede | d | No change | No, mo | ore effort needed |
| b. | . When doing leisure | activities | (at home or in | social situat | ions) |
| | Yes, less effort neede | d | No change | No, m | ore effort needed |
| 7. When | n completing your no | rmal daily | activities, do | you require: | |
| a. | When working (at a | job or vol | unteering): | | |
| | Fewer rest periods | Same | amount of rest p | periods | More rest periods |
| b. | When doing leisure Fewer rest periods | | • | | • |
| | ng your normal activit working (at a job or Shorter | volunteeri | _ | e are they: | iods that you take |
| | ng your normal activit doing leisure activiti | | _ | _ | • |
| | Shorter | The San | ne Length | Lo | onger |
| 10. How | would you rate your | ability to | deal with stres | s / stressful | situations? |
| No | ot Able to Deal as Well | D | eal the Same | _ A | ble to Deal More Effectively |
| 11. How | would you rate your | ability to | relax? | | |
| M | ore Able to Relax | Relax th | e Same | Not Able to | Relax as Well |
| | ou find you have mor | e energy t | o participate in | n social activ | vities with family, |

No change___

No, less energy_

Yes, more energy_

| Subject ID: | Subject Initials: | Date: Visit: |
|---------------------------|--------------------------------------|---------------------------|
| COMPARED TO 3 MO | NTHS AGO: | |
| 13. Has your physical a | bility to complete your normal d | laily activities changed? |
| Improved | Stayed the Same | Worsened |
| 14. Has your emotional | ability to cope with every day is | ssues changed? |
| Improved | Stayed the Same | Worsened |
| 15. Has your ability to p | participate in social activities cha | anged? |
| Improved | Stayed the Same | Worsened |
| 16. Has your endurance | level changed? | |
| Improved | Stayed the Same | Worsened |
| 17. Has your strength cl | nanged? | |
| Improved | Stayed the Same | Worsened |

| Date | Subject ID |
|------|------------|
| | |

SELF-PERCEPTION AND FUNCTION QUESTIONNAIRE

For questions 1-7, please choose one of the following responses and write the appropriate number in the space following the question.

| 1 | - | Strong | ly | disagree |
|---|---|--------|----|----------|
| | | | | |

- 2 Disagree
- 3 Agree

| | 4 - Strongly ag | ree | | | * |
|--|-------------------------|--------------|-----------|----------------|-----|
| 1. Things keep getting wo | rse as I get older. | | | | |
| 2. I can do just about anyt | hing I set my mind to. | | | | 7 |
| 3. I have as much pep as I | had last year. | | | | |
| 4. If I want something, I g | o out and get it. | | | | |
| 5. I feel that as I get older | I am less useful. | | | | |
| 6. I am as happy now as I | was when I was young | ger. | | | |
| 7. I am a go-getter | | | | | |
| For each statement/question for you. | on below, please circle | the response | that is r | nost appropria | ate |
| 8. As I get older, things a than I thought they wo | • | Better | Same | Worse | |
| 9. How much do you feel | l lonely? | Not much | | A lot | |
| 10. How satisfied are you | with your life today? | Satisfied | | Not satisfied | |
| 11. How would you descri | be your health status? | | | | |
| Improving | Remaining about | t the same | | Declining | |

| 12. | Which of the | following things | are you | physically | able to do? | (Please plac | e an X |
|-----|----------------|------------------|---------|------------|-------------|--------------|--------|
| | by each of the | e things you can | do.): | | | | |

—— Heavy work around the house (shoveling snow, washing floors, etc.)

____ Work at a full-time job

Ordinary work around the house

Walk half a mile

Go out to a movie, to church, to a meeting, or to visit friends or relatives

Walk up and down stairs

Best It Could Be

Worst Possible

Please place a mark on the line above that best represents your current state of health.

| S: | |
|-----------|-------------|
| Initials: | Ė |
| Subject | Subject ID. |
| Ś | Ū |
| | |

Visit #:

Date:

FATIGUE RATING / DAILY

Each day, after you have finished your normal activities, please rate your level of fatigue on a scale of 0-10.

'0' INDICATES NO FATIGUE, '10'INDICATES THE WORST FATIGUE POSSIBLE

| FATIGUE RATING | | | | | |
|--------------------|---|--|---|--|--|
| FATI | | | | | |
| DAY / DATE OF WEEK | - | | • | | |

| Subject Initials: | | |
|-------------------|--|--|
| Subject ID: | | |

PAIN LOG / DAILY

Date: Visit #:

*Please rate the average level of pain you felt each day on a scale of 0-10. '0' indicates no pain, '10' indicates the worst pain imaginable

| Subject ID: | Subject Initials: |
|-------------|-------------------|

| | * | |
|-------|---|----------|
| Date: | | Visit #: |
| | | |

ACTIVITY LOG

| For Each Activity, Estimate Distance Walked (in blocks) | | | | | | | | | |
|--|----------|-----------|----------|-----------|----------|-----------|----------|-----------|--|
| Activity | | | | | | | | | |
| Estimated Time Monitor On / Off | Time ON: | Time OFF: | |
| Day / Date of Week | | | | | | | | | |

APPENDIX III

THE EFFECT OF VARIATION OF NEUROMUSCULOSKELETAL MODEL CONTROL PARAMETERS ON PERFORMANCE DURING SIMULATED HUMAN WALKING

M. Talaty¹, M. Patel², A. Esquenazi¹, M. Klein³

1Gait and Motion Analysis Laboratory; Moss Rehab; 1200 West Tabor Road; Philadelphia, PA, USA e-mail: mctalaty@einstein.edu, web page: http://www.einstein.edu/gaitlab

² School of Biomedical Engineering, Sciences and Health Systems; Drexel University; 32nd & Chestnut Streets; Philadelphia, PA, USA

e-mail: mvp26@drexel.edu, web page: http://www.drexel.edu/biomed

3Moss Rehabilitation Research Institute; 1200 West Tabor Road; Philadelphia, PA, USA e-mail: mklein@einstein.edu, web page (linked from): http://www.einstein.edu

Keywords: Sensitivity analysis, Neuro-musculoskeletal model, Compensatory behavior

Abstract. The sensitivity of the walking performance of an established neuromusculoskeletal model to four major parameter groups was assessed to evaluate its robustness and response characteristics. Variables from the sensory system, the neural interconnectivity, the movement generator, and the postural controller groups were individually varied and the simulations rerun for each case. The range over which the parameters were varied was dictated by when the model could no longer walk. Overall, the model was robust in that it could walk over moderate to relatively large ranges of changes in each parameter group. The model was least sensitive to changes in the sensory parameters, exhibiting stable walking over a range of -30% to +82% of the baseline value. It showed a large range for the neural interconnectivity and postural controller variables. It showed stable walking for the smallest range, -10% to +20% for the rhythmic or movement controller variable. Continued testing will further elucidate the characteristics of the model responses and its similarity to that of a human. Intersegmental dynamics (or "induced acceleration") analysis will be used to assess how the model performance strategy differs from that of normal human walking. This may also be used to refine how the model responds.

1. Introduction

Understanding the compensatory or adaptive response of an individual with pathology is a critical component to evaluating treatment options. The clinician often aims to identify the primary deficit when a patient presents with a complicated gait deviation. As a simple example, a patient with stiff knee gait may circumduct the leg in order to gain

sufficient swing clearance necessary for limb advancement. However, the primary deviation is at the knee, not the hip. In more complicated cases, this identification may not be as obvious. Compensation often occurs naturally and automatically. Computer simulation of a musculoskeletal model that responds in a manner similar to a patient can be used to clarify the impairment-disability relationship and may allow for the prediction of outcomes of clinical interventions,

such as strengthening or a brace, to improve mobility.

Demonstrating that a model both walks and reacts to pathological changes like a human remains one obstacle to increasing the utility of computer simulation (Neptune 2000; Talaty 2002b). validation is a challenging task (van den Bogert, 1999). Application of the simple rule of, "If it walks like a duck, quacks like a duck,... then it must be a duck!" may be a useful guide to assessing the validity of a computer model. Relating this premise to a walking model, simply establishing that a model walks like a human does not ensure that it would react in the same way to pathology or resulting muscle weakness (Winter 1990; Wright 1999). "Quacking like a duck" or responding like a human may be a more critical evaluation criterion. Devising some well-conceived experimental paradigms to assess similarity of model response to that of a human can be informative. Congruence can lend to support that the model can be used to learn about the human system. This is a critical step, yet is not frequently reported in literature.

Sensitivity analysis is a necessary step to model evaluation and can provide a glimpse into model behavior as well. A model may be considered robust if it can perform as desired in the presence of noise or partially disrupted or altered inputs. Sensitivity analysis can assess robustness and whether the model performance depends strongly on one or more parameters. In the latter case, the values of these parameters should be established with maximum accuracy. Robustness is virtually a prerequisite in a study that aims to perturb a model as is the present Our intention is to introduce patterns of weakness to the model and learn about its compensatory response to that weakness profile. The behavior of a computer model depends on the scheme used to control it. The walking performance or behavior of the present model emerged out of the interaction of neural elements, mechanics of the body, and environmental constraints.

2. Methods

The model consisted of explicit representations of neural circuits and musculoskeletal elements. There were 8 segments, 7 joints, 20 muscles, 14 neural oscillators, and a two-part viscoelastic foot. It was capable of producing stable upright walking that closely resembled normal human gait after a few steps

of transient walking. Several key parameters such as the force of the rhythm or movement generator and of the posture controller, the level of sensory feedback, and the amount of interconnectivity between neural elements were perturbed in a sensitivity analysis to characterize model behavior.

2.1 The Model

A model has been implemented in which stable locomotion emerged through the global entrainment among the rhythmic activity of the neural system, the rhythmic movements of the musculo-skeletal system and the environmental constraints (Taga 1995). This approach was based in dynamical systems theory. The model was comprised of a distinct albeit considerably simplified neural system and a musculoskeletal system. There were separate subsystems incorporating sensory afferents, posture, and rhythmic movement. The main relationship that gave rise to the neural excitation was represented by a differential equation [1].

$$\tau_i \frac{d\dot{u}}{dt} = -u_i - \beta f(v_i) + \sum_{j=1}^{14} w_{ij}^0 f(u_j) + u_o + Q_i + S_i [1]$$

The neural excitation signal (u_{i+1}) was a result of the integration of inputs from the neural excitation of the previous instant (u_i) , inhibition (v_i) , neural interconnectivity (w_{ij}) , a constant tonic input (u_o) , neural oscillator coupling (Q_i) , and sensory inputs (S_i) . In short, the core neural system was represented by a group of simple oscillatory circuits called rhythm or central pattern generators (CPGs). CPG performance was modulated by sensory receptors and higher neural centers to produce relatively robust and flexible control.

The model could walk upright for an indefinite number of steps. Model walking closely resembled human walking. Compared to published normative data, the model showed reasonable progression and temporo-spatial parameters, joint ranges of motion and torque, and muscle activation (Table 1). Variational or sensitivity analyses was performed to understand the effect of parameter variation on performance and to clarify model behavior.

| Variable | Model Value | | | | |
|--------------------|--------------|--|--|--|--|
| Height | 1.8m | | | | |
| Weight | 70kg | | | | |
| Walking speed | 1.1 m/s | | | | |
| Stance/swing ratio | 64%/36% | | | | |
| Stride length | 1.3m | | | | |
| Hip range of | 15° ext./60° | | | | |
| motion | flex | | | | |
| Knee range of | 3° ext./ 78° | | | | |
| motion | flex | | | | |
| Ankle range of | 27° pf / 42° | | | | |
| motion | df | | | | |

Table 1. Anthropometric and steady state gait temporo-spatial and joint kinematic values of the model.

2.2 Sensitivity Analysis

The model sensitivity was tested by varying key parameters from each subsystem over the stable range of performance of the model. The following parameters were varied: strength or weight factors of the sensory input, the neural interconnectivity, the posture controller, and the rhythmic force or movement controller. Parameters in each subsystem were varied one at a time. However, each group of parameters was varied en masse. For example, when the sensory parameters were varied, the rhythm and posture controller and the neural interconnectivity variables were maintained at their baseline values. However, all eight variables (sensory input strengths) that gave rise to the actual the sensory contribution (S: in equation 1) to each of the fourteen neurons were simultaneously varied. A limit in a sensitivity parameter (group) was assumed when the model became unstable and fell over. Steady state model performance in each altered condition was compared to the steady state baseline performance. Steady state walking was usually obtained after about five to eight seconds of simulation time. Several whole body and joint temporal, kinematic, and kinetic parameters were evaluated to assess the effect of parameter changes on

model performance. Stride length, gait period, swing peak knee flexion, and peak knee torque were reported in this abstract.

3. Results

3.1 Sensory Parameter

The model was capable of walking with changes in this parameter over the range of 70% to 182% (Figure 1). Peak swing phase knee flexion and torque increased the strength of the sensory input beyond the baseline. The gait cycle time and stride length decreased. The reverse was found as the sensory parameter was decreased, except the gait period did not change. At the minimum, the model fell forwards.

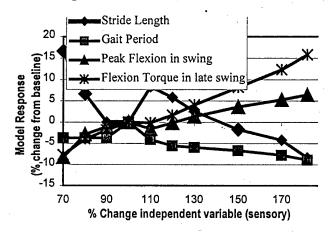


Figure 1. Model responses to changes in sensory parameter.

3.2 Neural Interconnectivity Parameter

The model could walk with changes in neural interconnectivity over the range of 56% to 145% (Figure 2). At minimum values of neural interconnectivity the model fell backwards; at maximum values, it fell forwards.

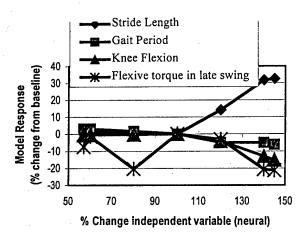


Figure 2. Model responses to changes in neural interconnectivity parameter.

3.3 Posture Controller Parameter

The model was capable of walking with changes in this parameter over the range of 87% to 170%. Stride length increased with this parameter up to about 110% after which it leveled off. The gait period showed a similar change. Knee flexion decreased as this parameter decreased.

3.4 Movement Controller Coefficient

The model was capable of walking with changes in this parameter over the range of 90% to 120%. An increase in this parameter caused a monotonic increase in the active knee torque, terminal stance phase knee flexion, and walking velocity where as the gait period decreased.

4. Discussion

Characterizing the model performance as its parameters varied helped to establish its robustness. The sensitivity analysis was one approach to characterizing model performance. The parameter variations were mathematical in nature. Each variable group was incremented and decremented by fixed percentages until the model could no longer walk in a stable manner. Interpretation of the results (model behavior) was done with a mathematical as well as a physiological perspective.

4.1 Interpretation of the Sensitivity Analysis

Model performance was less sensitive to changes in the sensory coefficient than to those in any of the other parameter groups. This variable group had the largest range over which the model performance was stable. Perhaps this coefficient was less critical to performance than the others. However, when the sensory coefficients were entirely eliminated (set to zero), the model was incapable of walking. This concurs with a commonly held belief in CPG theory (Grillner 1985). The model was more sensitive to decrease in sensory input rather than increase. Decreased knee flexion torque and swing phase knee flexion resulted in inadequate clearance and a forward fall. A minimum level of sensory input was required to cross the threshold of the neurons in the CPG to produce the muscle torque necessary for stable walking. Increasing the sensory input strength considerably resulted in hypersensitivity instability.

The model was robust to changes in neural interconnectivity, as evidenced by the large range over which stable walking was produced. As the values decreased, the lower extremities seemed to progress further than the trunk, eventually resulting in the trunk not keeping up with its support base. The model fell Neural interconnectivity was a mechanism for synergy among joints in the kinetic chain. Each leg joint received excitation from the other ipsilateral joints. The trunk received only input from the hips, and was perhaps more susceptible to isolation due to reduction in the connectivity parameter. As connectivity increased, the step length increased while knee flexion torque and knee flexion decreased resulting in improper toe clearance and a forward fall.

The model was more sensitive to decreases than to increases of the postural parameter. The postural controller acts mainly on extensor muscles and is thought to be responsible for maintaining a stable upright posture. The decreased mid-stance knee flexion observed with reduction of the postural parameter provided a mechanism for loss of stability and the fall of the model.

The model was the most sensitive to the coefficient of the rhythmic or movement controller. This parameter was directly related to active muscle force output during dynamic motor task performance. The narrow range (30%) for which the model walked was surprising. Patients with more profound weakness can walk. In this analysis, all these "strength" coefficients were simultaneously reduced, not just that of a single muscle group. Single muscle weakness analyses are underway.

There can be several levels on which to assess the computer simulation of a model. The ideal simulation would produce a walking pattern that was within the normal range and would perform in a manner exactly as a human would when perturbed. Only a similar walking pattern between the model and the human is not sufficient to establish that the model responds or adapts like a human. Establishing a similar control parameter profile may lend more support to humanlike responses. For example, EMG or joint moments have been compared to normal human profiles. Intersegmental dynamics analysis (IDA) or induced acceleration can provide another level of comparison of model control and performance. This analysis determines the specific contribution of joint moments or muscle forces to specific motions during gait. This analysis can help to evaluate where the model control and control strategy may differ from that of a normal human. Because IDA more directly relates a control parameter to performance, it may also guide some adjustment or refinement of the existing model control scheme.

5. Conclusions

The model was robust or not overly sensitive to changes in all of the tested variables. This lends support to use of such a model for perturbation analysis – for example to explore the effect of muscular weakness. It also suggests that the inherent structure (mechanics and information integration) provide considerable stability to model performance.

The complexity of the existing model makes defining the priorities by which it responds difficult. The rationale behind other simulation approaches is perhaps more evident. A tracking-based control scheme prioritizes obtaining a specific trajectory or walking pattern. An optimization-based control scheme prioritizes obtaining a specific cost – such as minimizing energy. In the present model, walking emerges from a complex series of interactions between subsystems and the environment. These subsystems are modeled after known and speculated principles in

human physiology. The ability of the model to walk as similarly to a human as it does suggests much of the necessary information was included and it was done so in a successful combination. The factors that give rise to compensation or adaptive responses in humans are complex and not well understood at present. Including more of the known aspects of human neuromuscular physiology may inherently account for some of the critical factors in the compensation response. Further testing the response characteristics of the present model can lend additional support to its utility for learning about human compensatory response in the presence of pathology.

6. Future Work

The model performance in other similar functional tasks to walking or in constrained walking tasks will be assessed. This will elucidate another aspect of the appropriateness of the model response.

Acceleration analysis can provide the basis for the addition of another control scheme. It is likely impossible to intuitively estimate what contribution a particular muscle or joint moment will have on a remote segment or joint. The use of computer models is essential to objectively determine the role of muscle during walking (Zajac 2003). It is planned to add a scheme that explicitly incorporates the potential or ability of each muscle group to compensate for specific muscle weaknesses. Such a scheme may either be layered on top of the existing control scheme or may simply replace it. Preliminary work has shown in normals that hip and knee moments contributed to restore ipsilateral ankle deficits in a manner consistent with the potential of each joint moment to assist (Talaty 2002a). This same work has shown that the acceleration components can be very sensitive to small changes in body orientation.

References

Grillner S. Neurological Bases of Rhythmic Motor Acts in Vertebrates. Science 1985; 228:143-149.

Neptune RR. Computer modeling and simulation of human movement (Applications in sport and rehabilitation). Physical Medicine and Rehabilitation Clinics of North America 2000; 11:417-434.

- Taga G. A Model of the Neuro-Musculo-Skeletal System for Human Locomotion I. Emergence of basic gait. Biological Cybernetics 1995; 73:97-111.
- Talaty MC. Intersegmental Dynamics Analysis of the Effect of an Ankle Foot Brace on Walking. Doctoral Dissertation. Biomedical Engineering and Science. Philadelphia: Drexel University, 2002:150.
- Talaty MC. Computer Modeling and Simulation in Gait Analysis. PM&R: State of the Art Reviews 2002; 16:339-360.
- Winter DA. Biomechanics and Motor Control of Human Movement. New York: Wiley Interscience Publication, 1990:277.
- Wright IC, Neptune RR, van den Bogert AJ, al. e. Validation of a 3D dynamic model of the human leg. Journal of Biomechanical Engineering 1999.
- van den Bogert AJ, Nigg BM. Simulation. In: Benno M. Nigg WH, ed. Biomechanics of the Musculo-Skeletal System. Chichester: Wiley, 1999:643.
- Zajac FE, Neptune RR, Kautz SA. Biomechanics and muscle coordination of human walking Part II: Lessons from dynamical simulations and clinical implications. Gait and Posture 2003; 17:1-17.